REMARKS/ARGUMENTS

This is a preliminary amendment in a RCE Application. The Office Action mailed April 20, 2004 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested. The claims presented for examination are: claims 1-19.

35 USC 103 Rejection

In numbered paragraph 4 of the Office Action mailed November 5, 2003 claims 1-19 were rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over the first primary Krulevitch et al reference (U.S. Patent No. 5,985,217) or the second primary Krulevitch et al reference (U.S. Patent No. 6,319,474) in view of the secondary Wilding et al reference (U.S. Patent No. 6,184,029).

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the first primary Krulevitch et al reference, U.S. Patent No. 5,985,217, and Applicants' invention defined by claims 1-19 includes the fact that the following elements of claims 1-19 are not found in the first primary Krulevitch et al reference:

> "a genetic region" or
>
> "a PCR reaction chamber section that is integral with said specimen treatment section or abuts said specimen treatment section" or
>
> "wherein said specimen treatment section includes another member bonded to said first mentioned member and having a plurality of microchannels therein, at least one of said

microchannels interconnecting said specimen chamber with said PCR reaction chamber section" or

"wherein said PCR reaction chamber is located in said another member, and includes at least one heater located in said another member" or

"additionally including at least one outlet and at least one microchannel connected to said PCR reaction chamber" or

"wherein said PCR reaction chamber section has a cross section greater than a cross section of said specimen treatment section" or

"wherein said cutter section and said specimen treatment section has a width less than a width of said PCR reaction chamber section" or

"wherein said PCR reaction chamber section is formed on a separate member than said specimen treatment section and is constructed to abut and align with said specimen treatment section such that fluid/sample passing through said specimen treatment section is directed into said PCR reaction chamber section" or

"wherein said PCR reaction chamber section is located on another substrate, constructed to abut with and align with said specimen treatment section to receive fluid/sample from said specimen treatment section" or

"a PCR reaction chamber section that is integral with said specimen treatment section or abuts said specimen treatment section and is constructed to receive fluid/sample from said specimen treatment section" or

"wherein said cutter section and said specimen treatment section have a width less than a width of said PCR reaction chamber section."

The differences between the second primary Krulevitch et al reference, U.S. Patent No. 6,319,474, and Applicants' invention defined by claims 1-19 includes the fact that the following elements of claims 1-19 are not found in the second primary Krulevitch et al reference:

"a genetic region" or

"a PCR reaction chamber section that is integral with said specimen treatment section or abuts said specimen treatment section" or

"wherein said specimen treatment section includes another member bonded to said first mentioned member and having a plurality of microchannels therein, at least one of said microchannels interconnecting said specimen chamber with said PCR reaction chamber section" or

"wherein said PCR reaction chamber is located in said another member, and includes at least one heater located in said another member" or

"additionally including at least one outlet and at least one microchannel connected to said PCR reaction chamber" or

"wherein said PCR reaction chamber section has a cross section greater than a cross section of said specimen treatment section" or

"wherein said cutter section and said specimen treatment section has a width less than a width of said PCR reaction chamber section" or

"wherein said PCR reaction chamber section is formed on a separate member than said specimen treatment section and is constructed to abut and align with said specimen treatment section such that fluid/sample passing through said specimen treatment section is directed into said PCR reaction chamber section" or

"wherein said PCR reaction chamber section is located on another substrate, constructed to abut with and align with said specimen treatment section to receive fluid/sample from said specimen treatment section" or

"a PCR reaction chamber section that is integral with said specimen treatment section or abuts said specimen treatment

section and is constructed to receive fluid/sample from said specimen treatment section" or

"wherein said cutter section and said specimen treatment section have a width less than a width of said PCR reaction chamber section."

The secondary Wilding et al reference is directed to sample fluid analysis, and particularly to blood analysis. The secondary Wilding et al reference does not show Applicants' instrument for biopsy and genetic analysis. The secondary Wilding et al reference shows only two PCR chambers in the many different versions of the devices described in the reference. A large number of the elements of Applicants' claims 1-19 are not found in the secondary Wilding et al reference. For example, the following elements of Applicants' claims 1-19 are not found in the secondary Wilding et al reference:

"a biopsy region" or

"a cutter section," or

"a specimen chamber located below said cutter section," or

"a specimen treatment section located adjacent said specimen chamber," or

"a PCR reaction chamber section that is integral with said specimen treatment section or abuts said specimen treatment section," or

"wherein said cutter section includes a member having an opening therein having a smooth cutting edge with atomic sharpness" or

"wherein said opening has a tapered configuration located adjacent said specimen chamber," or

"wherein said specimen treatment section includes another member bonded to said first mentioned member and having a plurality of microchannels therein, at least one of said microchannels interconnecting said specimen chamber with said PCR reaction chamber section," or

"additionally including an optical viewing arrangement adjacent said specimen treatment section," or

"wherein said PCR reaction chamber section has a cross section greater than a cross section of said specimen treatment section," or

"wherein said cutter section and said specimen treatment section has a width less than a width of said PCR reaction chamber section," or

"wherein said PCR reaction chamber section is formed on a separate member than said specimen treatment section and is constructed to abut and align with said specimen treatment section such that fluid/sample passing through said specimen treatment section is directed into said PCR reaction chamber section," or

"wherein said cutter section, said specimen chamber, and said specimen treatment section are located on one substrate, and wherein said PCR reaction chamber section is located on another substrate, constructed to abut with and align with said specimen treatment section to receive fluid/sample from said specimen treatment section," or

"wherein said cutter section is located in a member bonded to said one substrate and said specimen treating section is formed in said one substrate."

The MPEP section 706.02(j) "Contents of a 35 U.S.C. 103 Rejection," states: "First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)."

The 35 U.S.C. 103(a) rejection of Applicants' claims 1-19 over the first primary Krulevitch et al reference, the second primary Krulevitch et al reference, and the secondary Wilding et al reference fails all three of tests set out in MPEP section 706.02(j).

First, there is no teaching of combining the three references to meet Applicants' claims 1-19.

Second, there would be no reasonable expectation of success in combining the first primary Krulevitch et al reference, the second primary Krulevitch et al reference, and the secondary Wilding et al reference.

Third, the first primary Krulevitch et al reference, the second primary Krulevitch et al reference, and the secondary Wilding et al reference do not teach or suggest all the claim limitations.

Thus, the combination of the first primary Krulevitch et al reference, the second primary Krulevitch et al reference, and the secondary Wilding et al reference fails to support a rejection of the claims under 35 USC 103(a) and the rejection should be withdrawn.

Obviousness-Type Double Patenting Rejection

In numbered paragraph 5 of the Office Action mailed April 20, 2004 claims 1-19 were rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-15 of the Krulevitch '217 et al reference (U.S. Patent No. 5,985,217) in view of the Wilding et al reference (U.S. Patent No. 6,184,029).

The differences between the Krulevitch '217 et al reference and Applicants' invention defined by claims 1-19 includes the fact that the following elements of claims 1-19 are not found in the Krulevitch '217 et al reference:

"a genetic region" or

"a PCR reaction chamber section that is integral with said specimen treatment section or abuts said specimen treatment section" or

"wherein said specimen treatment section includes another member bonded to said first mentioned member and having a plurality of microchannels therein, at least one of said microchannels interconnecting said specimen chamber with said PCR reaction chamber section" or

"wherein said PCR reaction chamber is located in said another member, and includes at least one heater located in said another member" or

"additionally including at least one outlet and at least one microchannel connected to said PCR reaction chamber" or

"wherein said PCR reaction chamber section has a cross section greater than a cross section of said specimen treatment section" or

"wherein said cutter section and said specimen treatment section has a width less than a width of said PCR reaction chamber section" or

"wherein said PCR reaction chamber section is formed on a separate member than said specimen treatment section and is constructed to abut and align with said specimen treatment section such that fluid/sample passing through said specimen treatment section is directed into said PCR reaction chamber section" or

"wherein said PCR reaction chamber section is located on another substrate, constructed to abut with and align with said specimen treatment section to receive fluid/sample from said specimen treatment section" or

"a PCR reaction chamber section that is integral with said specimen treatment section or abuts said specimen treatment section and is constructed to receive fluid/sample from said specimen treatment section" or

"wherein said cutter section and said specimen treatment section have a width less than a width of said PCR reaction chamber section."

The Wilding et al reference does not show Applicants' instrument for biopsy and genetic analysis. A large number of the elements of Applicants' claims 1-19 are not found in the Wilding et al reference. For example, the following elements of Applicants' claims 1-19 are not found in the Wilding et al reference:

"a biopsy region" or

"a cutter section," or

"a specimen chamber located below said cutter section," or

"a specimen treatment section located adjacent said specimen chamber," or

"a PCR reaction chamber section that is integral with said specimen treatment section or abuts said specimen treatment section," or

"wherein said cutter section includes a member having an opening therein having a smooth cutting edge with atomic sharpness" or

"wherein said opening has a tapered configuration located adjacent said specimen chamber," or

"wherein said specimen treatment section includes another member bonded to said first mentioned member and having a plurality of microchannels therein, at least one of said microchannels interconnecting said specimen chamber with said PCR reaction chamber section," or

"additionally including an optical viewing arrangement adjacent said specimen treatment section," or

"wherein said PCR reaction chamber section has a cross section greater than a cross section of said specimen treatment section," or

"wherein said cutter section and said specimen treatment section has a width less than a width of said PCR reaction chamber section," or

"wherein said PCR reaction chamber section is formed on a separate member than said specimen treatment section and is constructed to abut and align with said specimen treatment section such that fluid/sample passing through said specimen treatment section is directed into said PCR reaction chamber section," or

"wherein said cutter section, said specimen chamber, and said specimen treatment section are located on one substrate, and wherein said PCR reaction chamber section is located on another substrate, constructed to abut with and align with said specimen treatment section to receive fluid/sample from said specimen treatment section," or

"wherein said cutter section is located in a member bonded to said one substrate and said specimen treating section is formed in said one substrate."

In determining "obviousness," "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. There must be a reasonable expectation of success. The prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)."

The rejection of Applicants' claims 1-19 under the judicially created doctrine of obviousness-type double patenting over claims 1-15 of the Krulevitch '217 et al reference (U.S. Patent No. 5,985,217) in view of the Wilding et al reference (U.S. Patent No. 6,184,029) fails all of the tests.

First, there is no teaching of combining the Krulevitch '217 et al reference and the Wilding et al reference to meet Applicants' claims 1-19.

Second, there would be no reasonable expectation of success in combining the Krulevitch '217 et al reference and the Wilding et al reference.

Third, the Krulevitch '217 et al reference and the Wilding et al reference do not teach or suggest all the claim limitations.

Thus, the combination of the Krulevitch '217 et al reference and the secondary Wilding et al reference fails to support a rejection of the claims under the judicially created doctrine of obviousness-type double patenting and the rejection should be withdrawn.

Obviousness-Type Double Patenting Rejection

In numbered paragraph 6 of the Office Action mailed April 20, 2004 claims 1-19 were rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 17 of the Krulevitch '474 et al reference (U.S. Patent No. 6,319,474) in view of the Wilding et al reference (U.S. Patent No. 6,184,029).

The differences between the Krulevitch '474 et al reference and Applicants' invention defined by claims 1-19 includes the fact that the following elements of claims 1-19 are not found in the Krulevitch '474 et al reference:

"a genetic region" or

"a PCR reaction chamber section that is integral with said specimen treatment section or abuts said specimen treatment section" or

"wherein said specimen treatment section includes another member bonded to said first mentioned member and having a plurality of microchannels therein, at least one of said microchannels interconnecting said specimen chamber with said PCR reaction chamber section" or

"wherein said PCR reaction chamber is located in said another member, and includes at least one heater located in said another member" or

"additionally including at least one outlet and at least one microchannel connected to said PCR reaction chamber" or

"wherein said PCR reaction chamber section has a cross section greater than a cross section of said specimen treatment section" or

"wherein said cutter section and said specimen treatment section has a width less than a width of said PCR reaction chamber section" or

"wherein said PCR reaction chamber section is formed on a separate member than said specimen treatment section and is constructed to abut and align with said specimen treatment section such that fluid/sample passing through said specimen treatment section is directed into said PCR reaction chamber section" or

"wherein said PCR reaction chamber section is located on another substrate, constructed to abut with and align with said specimen treatment section to receive fluid/sample from said specimen treatment section" or

"a PCR reaction chamber section that is integral with said specimen treatment section or abuts said specimen treatment section and is constructed to receive fluid/sample from said specimen treatment section" or

"wherein said cutter section and said specimen treatment section have a width less than a width of said PCR reaction chamber section."

The Wilding et al reference does not show Applicants' instrument for biopsy and genetic analysis. A large number of the elements of Applicants' claims 1-19 are not found in the Wilding et al reference. For example, the following elements of Applicants' claims 1-19 are not found in the Wilding et al reference:

"a biopsy region" or

"a cutter section," or

"a specimen chamber located below said cutter section," or

"a specimen treatment section located adjacent said specimen chamber," or

"a PCR reaction chamber section that is integral with said specimen treatment section or abuts said specimen treatment section," or

"wherein said cutter section includes a member having an opening therein having a smooth cutting edge with atomic sharpness" or

"wherein said opening has a tapered configuration located adjacent said specimen chamber," or

"wherein said specimen treatment section includes another member bonded to said first mentioned member and having a plurality of microchannels therein, at least one of said microchannels interconnecting said specimen chamber with said PCR reaction chamber section," or

"additionally including an optical viewing arrangement adjacent said specimen treatment section," or

"wherein said PCR reaction chamber section has a cross section greater than a cross section of said specimen treatment section," or

"wherein said cutter section and said specimen treatment section has a width less than a width of said PCR reaction chamber section," or

"wherein said PCR reaction chamber section is formed on a separate member than said specimen treatment section and is constructed to abut and align with said specimen treatment section such that fluid/sample passing through said specimen treatment section is directed into said PCR reaction chamber section," or

"wherein said cutter section, said specimen chamber, and said specimen treatment section are located on one substrate, and wherein said PCR reaction chamber section is located on another substrate, constructed to abut with and align with said specimen treatment section to receive fluid/sample from said specimen treatment section," or

"wherein said cutter section is located in a member bonded to said one substrate and said specimen treating section is formed in said one substrate."

In determining "obviousness," "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. There must be a reasonable expectation of success. The prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)."

The rejection of Applicants' claims 1-19 under the judicially created doctrine of obviousness-type double patenting over claims 1-15 of the Krulevitch '474 et al reference (U.S. Patent No. 5,985,474) in view of the Wilding et al reference (U.S. Patent No. 6,184,029) fails all of the tests.

First, there is no teaching of combining the Krulevitch '474 et al reference and the Wilding et al reference to meet Applicants' claims 1-19.

Second, there would be no reasonable expectation of success in combining the Krulevitch '474 et al reference and the Wilding et al reference.

Third, the Krulevitch '474 et al reference and the Wilding et al reference do not teach or suggest all the claim limitations.

Thus, the combination of the Krulevitch '474 et al reference and the secondary Wilding et al reference fails to support a rejection of the claims under the judicially created doctrine of obviousness-type double patenting and the rejection should be withdrawn.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated April 20, 2004 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,

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Livermore, California
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